used to treat other disorders involving lumens or lumen-like vessels in the body such as prostatitis, the delivery of cancer chemotherapeutics, and the site specific delivery of controlled release antibiotics for the treatment of pericarditis, myocarditis, or endocarditis.

The present invention may also be used for delivering agents to the myocardium which have cardioprotective effects on myocardium exposed to a global or sub-global ischemic insult i.e. induced cardiologia during an "open heart" operation in which it is necessary to stop the heart and put the patient on cardiopulmonary bypass. Possible agents to be delivered include heat-shock proteins, hormones, ATP and its biochemical precursors, glucose or other metabolic carbohydrates. The treatment can allow the heart to recover function quicker after re-perfusion by reducing the "myocardial stunning" that occurs due to global ischemia.

The foregoing description of the preferred embodiments of the present invention has been presented for purposes of illustration and description. The disclosed embodiments are not intended to be exhaustive or to limit the invention to the precise forms disclosed, and obviously many modifications and variations are possible in light of the above teachings. It is intended that the scope of the invention be defined by the following claims, including all equivalent.

We claim:

1. A method of treating a vessel having a vessel wall with an inner surface, the method comprising the steps of:

inserting a catheter having a vessel puncturing element disposed therein into a substantially tubular vessel;

positioning the puncturing element at the site in the vessel to be treated;

restraining said puncturing element such that it is maintained in a retracted position;

placing said puncturing element in a puncturing position in which said puncturing element is no longer restrained;

said puncturing element automatically moving in a direction substantially non-parallel with respect to a portion of said catheter that contains said puncturing element when said puncturing element is no longer being restrained.

2. The method of claim 1 further comprising the step of puncturing the vessel wall with the puncturing element at the site to be treated.

3. The method of claim 2 further comprising the step of delivering via a delivery means a drug outside of the inner surface of the vessel wall through the puncture in the vessel wall.

4. The method of claim 3 wherein the step of delivering the drug comprises delivering the drug into the vessel wall.

5. The method of claim 3 wherein the step of delivering the drug comprises delivering the drug to the outer surface of the vessel wall.

6. The method of claim 3 wherein the step of delivering the drug comprises delivery of the drug into tissue surrounding the vessel wall.

7. The method of claim 3 wherein the step of delivering the drug comprises the step of delivering a drug in a time release module.

8. The method of claim 3 wherein the delivery means includes said puncturing element having a drug delivery lumen and wherein the step of delivering the drug comprises delivering the drug through the drug delivery lumen.

9. The method of claim 1 wherein said drug comprises an antiproliferative drug for the treatment of restenosis.

10. The method of claim 1 wherein said drug comprises an antiproliferative drug for the treatment of vascular disease.

11. The method of claim 1 wherein said drug comprises a specific inhibitor of cellular proliferation.

12. The method of claim 1 wherein said drug comprises a specific inhibitor of thrombin.

13. The method of claim 1 wherein said drug comprises a specific inhibitor of platelets.

14. The method of claim 1 wherein said drug comprises a genetic material.

15. The method of claim 1 wherein said drug comprises a genetic material that when incorporated into cells results in the expression of therapeutic materials.

16. The method of claim 1 wherein said drug is incorporated into a time released matrix.

17. A method of treating a vessel having a vessel wall with an inner surface, the method comprising the steps of:

inserting a catheter having a vessel puncturing element disposed therein into a substantially tubular vessel;

positioning the puncturing element at the site in the vessel to be treated;

inflating an inflatable compartment adjacent said puncturing element to thereby apply an adjacent force adjacent said puncturing element to move said puncturing element in a direction substantially non-parallel with respect to a portion of said catheter that contains said puncturing element, said adjacent force moving said puncturing element from a retracted position to a puncturing position.

18. The method of claim 17 further comprising the step of puncturing the vessel wall with the puncturing element.

19. The method of claim 18 further comprising the step of delivering via a delivery means a drug outside of the inner surface of the vessel wall through the puncture in the vessel wall.

20. The method of claim 19 wherein the step of delivering the drug comprises delivering the drug into the vessel wall.

21. The method of claim 19 wherein the step of applying said force moves said puncturing element a predetermined distance such that said drug is delivered to an outer surface of the vessel wall.

22. The method of claim 19 wherein the step of delivering the drug comprises delivery of the drug into tissue surrounding the vessel wall.

23. The method of claim 19 wherein the step of delivering the drug comprises the step of delivering a drug in a time release module.

24. The method of claim 19 wherein the delivery means includes said puncturing element having a drug delivery lumen and wherein the step of delivering the drug comprises delivering the drug through the drug delivery lumen.

25. The method of claim 17 wherein said compartment inflates a predetermined amount to move said puncturing element a predetermined distance.

26. A drug delivery device for treating a vessel having a vessel wall with an inner surface, the device comprising:

an elongated catheter adapted to be inserted into the vessel;

said catheter comprising a puncturing element having a retracted position in which said puncturing element does not puncture said vessel wall, at least a portion of said puncturing element being housed in a portion of said catheter when said puncturing element is in said retracted position;

a restraint that contacts and holds said puncturing element in said retracted position;

said puncturing element further having a puncturing position in which said puncturing element engages and

punctures said vessel wall, said puncturing element being substantially non-parallel with respect to said portion of said catheter when said puncturing element is in said puncturing position;

said puncturing element automatically moving from said retracted position to said puncturing position when said restraint is no longer being applied; and

delivery means coupled to said catheter and delivering a drug through a puncture in the vessel wall.

27. The device defined in claim 26 wherein:

said puncturing element further comprises a puncturing tip for puncturing said vessel wall when said puncturing element is in said puncturing position; and

said catheter further comprises a window through which said puncturing tip extends when said puncturing element is in said puncturing position.

28. The device defined in claim 26 wherein said catheter further comprises:

an inflatable balloon coupled to said catheter; and

an inflation lumen extending through said catheter for delivering inflation fluid to said balloon.

29. The device defined in claim 26 wherein:

said puncturing element further comprises an elongated shaft having a proximal and a distal end and an inner shaft lumen, and a needle, attached to said distal end of said shaft, having an inner needle lumen which is in fluid communication with said inner shaft lumen; and

said delivery means comprises said inner shaft lumen and said inner needle lumen.

30. The device defined in claim 29 wherein said needle further comprises a puncturing tip for engaging and puncturing said vessel wall when said puncturing element is in said puncturing position.

31. The device defined in claim 30 wherein said puncturing tip includes an opening in communication with said inner needle lumen so that fluid in said inner needle lumen can flow out of said tip opening.

32. The device defined in claim 31 wherein said delivery means further comprises an injection device coupled to said inner shaft lumen for injecting fluid through said inner shaft lumen.

33. The device defined in claim 30 wherein said puncturing tip has a beveled edge for puncturing said vessel wall.

34. The device defined in claim 26 wherein said puncturing element comprises a needle having a tip for puncturing said vessel wall.

35. The device defined in claim 34 wherein:

said needle is bent into a substantially U-shape when said puncturing element is in said retracted position; and

said needle is extended out to form a predetermined angle when said needle is in said puncturing position.

36. The device defined in claim 34 wherein:

said needle is bent to a first predetermined angle when said puncturing element is in said retracted position; and

said needle is extended out to form a second predetermined angle when said needle is in said puncturing position.

37. The device defined in claim 34 wherein said needle is substantially parallel with said portion of said catheter when said needle is in said retracted position, said needle also being substantially non-parallel with said portion of said catheter when said needle is in said puncturing position.

38. A drug delivery device for treating a vessel having a vessel wall with an inner surface, the device comprising:

an elongated catheter adapted to be inserted into the vessel;

said catheter comprising a puncturing element having a retracted position in which said puncturing element does not puncture said vessel wall, at least a portion of said puncturing element being housed in a portion of said catheter when said puncturing element is in said retracted position;

said puncturing element further having a puncturing position in which said puncturing element engages and punctures said vessel wall, said puncturing element being substantially non-parallel with respect to said portion of said catheter when said puncturing element is in said puncturing position;

a movable surface comprising an inflatable compartment coupled to said catheter and adjacent said puncturing element to contact and move said puncturing element from said retracted position to said puncturing position when said movable surface is moved toward said puncturing element.

39. The device of claim **38** wherein said movable surface is moved toward said puncturing element by inflating said inflatable compartment.

40. The device of claim **38** further comprising delivery means coupled to said catheter for delivering a drug outside the inner surface of the vessel wall through a puncture in the vessel wall.

41. The device defined in claim **40** wherein:

said puncturing element further comprises a puncturing tip for puncturing said vessel wall when said puncturing element is in said puncturing position; and

said catheter further comprises a window through which said puncturing tip extends when said puncturing element is in said puncturing position.

42. The device defined in claim **40** wherein:

said inflatable compartment comprises an inflatable balloon; and

an inflation lumen extends through said catheter for delivering inflation fluid to said balloon.

43. The device defined in claim **40** wherein:

said puncturing element further comprises an elongated shaft having a proximal and a distal end and an inner shaft lumen, and a needle, attached to said distal end of said shaft, having an inner needle lumen which is in fluid communication with said inner shaft lumen; and

said delivery means comprises said inner shaft lumen and said inner needle lumen.

44. The device defined in claim **43** wherein said needle further comprises a puncturing tip for engaging and puncturing said vessel wall when said puncturing element is in said puncturing position.

45. The device defined in claim **44** wherein said puncturing tip includes an opening in communication with said inner needle lumen so that fluid in said inner needle lumen can flow out of said tip opening.

46. The device defined in claim **45** wherein said delivery means further comprises an injection device coupled to said inner shaft lumen for injecting fluid through said inner shaft lumen.

47. The device defined in claim **46** wherein said puncturing tip has a beveled edge for puncturing said vessel wall.

48. The device of claim **40** wherein said drug comprises an antiproliferative drug for the treatment of restenosis.

49. The device of claim **40** wherein said drug comprises an antiproliferative drug for the treatment of vascular disease.

50. The device of claim 40 wherein said drug comprises a specific inhibitor of cellular prolifcration.

51. The device of claim 40 wherein said drug comprises a specific inhibitor of thrombin.

52. The device of claim 40 wherein said drug comprises a specific inhibitor of platelets.

53. The device of claim 40 wherein said drug comprises a genetic material.

54. The device of claim 40 wherein said drug comprises a genetic material that when incorporated into cells results in the expression of therapeutic materials.

55. The device of claim 40 wherein said drug is incorporated into a time released matrix.

56. The device defined in claim 38 wherein said puncturing element comprises a needle having a tip for puncturing said vessel wall.

* * * * *

57. An intravascular therapeutic catheter comprising:

an elongate catheter body having a distal portion;

a tissue penetrating member disposed proximate the distal portion having a first non-penetrating position and a second tissue penetrating position; and

an actuator member disposed proximate the distal portion for moving the tissue penetrating member from one of the first or second positions to the other of the first or second positions, the actuator adding energy to the tissue penetrating member as the tissue penetrating member moves from the first position to the second position.

58. An intravascular therapeutic catheter as in claim 57, wherein the actuator member comprises a balloon.

59. An intravascular therapeutic catheter as in claim 57, wherein the catheter body has a longitudinal axis, and the tissue penetrating member moves along a substantially lateral path with respect to the axis.

60. An intravascular therapeutic catheter as in claim 59, wherein the actuator member moves the tissue penetrating member a limited distance along the lateral path.

61. An intravascular therapeutic catheter as in claim 57, wherein the actuator member moves the tissue penetrating member a limited distance.

62. An intravascular therapeutic catheter as in claim 57 wherein the tissue penetrating member includes a

plurality of needles, each needle coupled to the actuator means for simultaneous operation.

63. An intravascular therapeutic catheter as in claim 62 wherein each needle of the tissue penetrating member includes a tip, the tip beveled at an angle.

~~64~~ 59. An intravascular therapeutic catheter as in claim 58 further including:

an inflation fluid source fluidly coupled to the balloon to fill the balloon, thereby adding energy to the tissue penetrating member.

~~65~~ 63. An intravascular therapeutic catheter as in claim 57 wherein the tissue penetrating member is a single needle.

~~66~~ 64. An intravascular therapeutic catheter as in claim ~~65~~ 63 wherein the tissue penetrating member includes a tip beveled at an angle.

67. An intravascular therapeutic catheter as in claim 57 further comprising

a fluid delivery lumen located in the catheter body extending from a proximal portion to a position proximate the tissue penetrating member for delivering a fluid to the location of the tissue penetrating member.

~~68~~ 66. An intravascular therapeutic catheter of claim ~~67~~ 65 further comprising:

a fluid delivery lumen located in the tissue penetrating member coupled to the fluid delivery lumen located in

the catheter body for delivering a fluid through the tissue penetrating member.

67 ~~69~~. An intravascular therapeutic catheter of claim 66 ~~68~~ wherein the tissue penetrating member is a single needle having a tip, whereby fluid is delivered from the needle tip.

Sub A3 70. An intravascular therapeutic catheter as in claim 57 wherein:

the tissue penetrating member is adapted for rotary motion about a pivot point between the first non-penetrating position and the second tissue penetrating position; and

the second position is defined by maximum storage of energy in the tissue penetrating member thereby defining motion over a limited distance.

69 ~~71~~. An intravascular therapeutic catheter of claim 68 ~~70~~ wherein the actuator member includes:

an inflation source connected to an inflation balloon located proximate the tissue penetrating member at a position near the pivot point for moving the tissue penetrating member with respect to the catheter body whereby the penetrating member moves from the first position to the second position.

70 ~~72~~. An intravascular therapeutic catheter as in claim ~~57~~ wherein the actuator and the tissue penetrating member are integrally formed.

11 ~~73.~~ 57 An intravascular therapeutic catheter as in claim ~~57~~ wherein the actuator and the tissue penetrating member are separate parts.

Sub A4 74. An intravascular therapeutic catheter comprising:
an elongate catheter body having a distal portion;
a tissue penetrating member disposed proximate the distal portion having a first non-penetrating position and a second tissue penetrating position; and
an actuator member disposed proximate the distal portion for moving the tissue penetrating member from one of the first or second positions to the other of the first or second positions, the tissue penetrating member releasing stored energy as the penetrating member moves from the first position to the second position.

75. An intravascular therapeutic catheter as in claim 74, wherein the first position of the penetrating member is a constrained position where the tissue penetrating member is located within a constraining lumen, and wherein the second position is an unconstrained position where the tissue penetrating member is not constrained by the constraining lumen.

14 ~~76.~~ 73 An intravascular therapeutic catheter as in claim ~~75,~~ wherein the tissue penetrating member moves about a pivot point from the first position to the second position.

15 ~~77.~~ 72 An intravascular therapeutic catheter as in claim ~~74,~~ wherein the tissue penetrating member moves from one of

the first or second positions to the other of the first or second positions about a pivot point.

Sub A5

78. An intravascular therapeutic catheter of claim 74 wherein:

the tissue penetrating member is adapted for rotary motion about a pivot point between the first non-penetrating position and the second tissue penetrating position; and

the second position is defined by complete release of the stored energy thereby defining motion over a limited distance.

77 76

~~79~~. An intravascular therapeutic catheter of claim ~~78~~ wherein the actuator member includes:

a stylet connected to the tissue penetrating member at a position near the pivot point for moving the tissue penetrating member with respect to the catheter body whereby the penetrating member moves from the first position to the second position.

78 72

~~80~~. An intravascular therapeutic catheter as in claim ~~74~~ wherein the actuator and the tissue penetrating member are integrally formed.

79 72

~~81~~. An intravascular therapeutic catheter as in claim ~~74~~ wherein the actuator and the tissue penetrating member are separate parts.

Sub A6

82. An intravascular therapeutic catheter comprising:

an elongate catheter body having distal portion, and having an axis;

a tissue penetrating member disposed proximate the distal portion having a first non-penetrating position and a second tissue penetrating position and having a pivot point; and

an actuator member disposed proximate the distal portion for moving the tissue penetrating member from one of the first or second positions to the other of the first or second positions about the pivot point.

83. An intravascular therapeutic catheter as in claim 82, wherein the actuator member moves the tissue penetrating member from a constraining lumen within the catheter.

82 80

84. An intravascular therapeutic catheter as in claim ~~82~~ wherein the actuator and the tissue penetrating member are integrally formed.

83 80

85. An intravascular therapeutic catheter as in claim ~~82~~ wherein the actuator and the tissue penetrating member are separate parts.

Sub A7

86. An intravascular therapeutic catheter comprising:

an elongate catheter body having a distal portion and an axis;

a tissue penetrating member disposed proximate the distal portion having a first non-penetrating position and a second tissue penetrating position; and

an actuator member disposed proximate the distal portion for moving the tissue penetrating member from one of the first or second positions to the other of the first

or second positions in a substantially lateral path with respect to the axis.

85 84
87. An intravascular therapeutic catheter as in claim 86, wherein the actuator member comprises a balloon located proximate the tissue penetrating member.

84 84
88. An intravascular therapeutic catheter as in claim 86, wherein the actuator member moves the tissue penetrating member a limited distance.

87 84
89. An intravascular therapeutic catheter as in claim 86, wherein the actuator and the tissue penetrating member are integrally formed.

84 84
90. An intravascular therapeutic catheter as in claim 86, wherein the actuator and the tissue penetrating member are separate parts.

Cancel A8
91. An intravascular therapeutic catheter comprising:
an elongate catheter body having a distal portion and an axis;
a tissue penetrating member disposed proximate the distal portion having a first non-penetrating position and a second tissue penetrating position; and
an actuator member disposed proximate the distal portion for moving the tissue penetrating member a limited distance from one of the first or second positions to the other of the first or second positions.

90 89
92. An intravascular therapeutic catheter as in claim 91, wherein the actuator member comprises a balloon located

on the catheter body proximate the tissue penetrating member.

Sub a9

93. An intravascular therapeutic catheter as in claim 91, wherein the actuator member moves the tissue penetrating member along a lateral path with respect to a longitudinal axis of the catheter body.

92 89

~~94.~~ An intravascular therapeutic catheter as in claim ~~91~~, wherein the tissue penetrating member comprises a single needle.

95. An intravascular therapeutic catheter as in claim 91, wherein the tissue penetrating member comprises a plurality of needles.

93 89

~~96.~~ An intravascular therapeutic catheter as in claim ~~91~~, wherein the tissue penetrating member is heated.

Sub a10

97. An intravascular therapeutic catheter as in claim 91, wherein the tissue penetrating member is cold.

95 89

~~98.~~ An intravascular therapeutic catheter as in claim ~~91~~, wherein the tissue penetrating member is adapted for vibration, and whereby vibration of the needle facilitates therapy.

94 89

~~99.~~ An intravascular therapeutic catheter as in claim ~~91~~, further comprising

a fluid delivery lumen located in the catheter body extending from a proximal portion of the catheter body to a position proximate the tissue penetrating member

for delivering a fluid to the location of the tissue penetrating member.

97 89
~~100.~~ An intravascular therapeutic catheter as in claim ~~91~~, wherein the tissue penetrating member comprises a needle having a tip, the tip being beveled to facilitate tissue puncture.

98 89
~~101.~~ An intravascular therapeutic catheter as in claim ~~91~~ wherein the actuator and the tissue penetrating member are integrally formed.

99 89
~~102.~~ An intravascular therapeutic catheter as in claim ~~91~~ wherein the actuator and the tissue penetrating member are separate parts.

103. A method for treating cardiac tissue comprising the steps of:

providing an intravascular therapeutic catheter having an elongate catheter body, an actuator and a tissue penetrating member disposed proximate a distal portion of the catheter body, the tissue penetrating member having a first non-penetrating position and a second tissue penetrating position;

navigating the catheter through vasculature to a treatment site; and

adding energy to the tissue penetrating member to move the tissue penetrating member from the first position to the second position.

101 100
~~104.~~ A method for treating cardiac tissue as in claim ~~103~~ wherein the catheter further comprises an actuation balloon located proximate the tissue penetrating member

for moving the tissue penetrating member; and wherein energy is added to the tissue penetrating member by inflating the actuation balloon.

102 100
105. A method for treating cardiac tissue as in claim 103 wherein the tissue penetrating member is movable along a substantially lateral path with respect to a longitudinal axis of the catheter body from the first position to the second position.

103 102
106. A method for treating cardiac tissue as in claim 105 wherein the penetrating member is movable a limited distance along the lateral path.

104 100
107. A method for treating cardiac tissue as in claim 103 wherein the tissue penetrating member is movable a limited distance from the first position to the second position.

105 100
108. A method of treating cardiac tissue as in claim 103 wherein the actuator and the tissue penetrating member are integrally formed.

106 100
109. A method of treating cardiac tissue as in claim 103 wherein the actuator and the tissue penetrating member are separate parts.

Seek A 12/

110. A method for treating cardiac tissue comprising the steps of:

providing an intravascular therapeutic catheter having an elongate catheter body, an actuator and a tissue penetrating member disposed proximate a distal portion

of the catheter body, the tissue penetrating member having a first non-penetrating position and a second tissue penetrating position;

navigating the catheter through vasculature to a treatment site; and

releasing energy from the tissue penetrating member to move the tissue penetrating member from the first position to the second position.

106 107
~~111~~. A method for treating cardiac tissue as in claim ~~110~~ wherein the intravascular therapeutic catheter further comprises a restraint located proximate the tissue penetrating member for retaining the tissue penetrating member in the first position; and wherein energy is released from the tissue penetrating member by moving the tissue penetrating member relative to the restraint.

109 108
~~112~~. A method for treating cardiac tissue as in claim ~~111~~ wherein the tissue penetrating member is movable about a pivot point from the first position to the second position, whereby the tissue penetrating member moves about the pivot point from the first position to the second position upon releasing energy from said tissue penetrating member.

110 107
~~113~~. A method for treating cardiac tissue as in claim ~~110~~ wherein the tissue penetrating member is movable about a pivot point from the first position to the second position, whereby the tissue penetrating member moves about the pivot point from the first position to the second position upon releasing energy from said tissue penetrating member.

111 107
~~114~~. A method of treating cardiac tissue as in claim ~~110~~ wherein the actuator and the tissue penetrating member are integrally formed.

112 107
~~115~~. A method of treating cardiac tissue as in claim ~~110~~ wherein the actuator and the tissue penetrating member are separate parts.

Sub A13

116. A method for treating cardiac tissue comprising the steps of:

providing an intravascular therapeutic catheter having an elongate catheter body, an actuator and a tissue penetrating member disposed proximate a distal portion of the catheter body, the tissue penetrating member having a pivot point, a first non-penetrating position and a second tissue penetrating position;

navigating the catheter through vasculature to a treatment site; and

moving the tissue penetrating member from one of the first or second positions to the other of the first or second positions about the pivot point.

117. A method for treating cardiac tissue as in claim 116 wherein the tissue penetrating member is restrainable in a restraint lumen; and wherein the step of moving the tissue penetrating member further comprises moving the tissue penetrating member from the restraint lumen whereby the tissue penetrating member moves from one of the first or second positions to the other of the first or second positions about the pivot point.

115 113
~~118.~~ A method of treating cardiac tissue as in claim ~~116~~ wherein the actuator and the tissue penetrating member are integrally formed.

116 113
~~119.~~ A method of treating cardiac tissue as in claim ~~116~~ wherein the actuator and the tissue penetrating member are separate parts.

Sub A 14

120. A method for treating cardiac tissue comprising the steps of:

providing an intravascular therapeutic catheter having an elongate catheter body, an actuator and a tissue penetrating member disposed proximate a distal portion of the catheter body, the tissue penetrating member having a first non-penetrating position and a second tissue penetrating position;

navigating the catheter through vasculature to a treatment site; and

moving the tissue penetrating member from one of the first or second positions to the other of the first or second positions in a substantially lateral path with respect to a longitudinal axis of the catheter body.

114 117
~~121.~~ A method for treating cardiac tissue as in claim ~~120~~ wherein the catheter further comprises an actuation balloon located proximate the tissue penetrating member; and wherein the step of moving the tissue penetrating member is performed by inflating the actuation balloon.

119 117
~~122.~~ A method for treating cardiac tissue as in claim ~~120~~ wherein the tissue penetrating member is moved a limited distance along the substantially lateral path.

120 117
~~123~~. A method of treating cardiac tissue as in claim ~~120~~ wherein the actuator and the tissue penetrating member are integrally formed.

121 117
~~124~~. A method of treating cardiac tissue as in claim ~~120~~ wherein the actuator and the tissue penetrating member are separate parts.

Sub A15

125. A method for treating cardiac tissue comprising the steps of:

providing an intravascular therapeutic catheter having an elongate catheter body, an actuator and a tissue penetrating member disposed proximate a distal portion of the catheter body, the tissue penetrating member having a first non-penetrating position and a second tissue penetrating position;

navigating the catheter through vasculature to a treatment site; and

moving the tissue penetrating member a limited distance from one of the first or second positions to the other of the first or second positions.

123 122
~~126~~. A method for treating cardiac tissue as in claim ~~125~~ wherein the catheter further comprises an actuator balloon located proximate the tissue penetrating member; and wherein the step of moving the tissue penetrating member is performed by inflating the actuation balloon.

124 123
~~127~~. A method for treating cardiac tissue as in claim ~~126~~ wherein the tissue penetrating member is moved along a

lateral path with respect to a longitudinal axis of the catheter body.

125 122
~~120~~ A method of treating cardiac tissue as in claim ~~125~~ wherein the actuator and the tissue penetrating member are integrally formed.

124 122
~~129~~. A method of treating cardiac tissue as in claim ~~125~~ wherein the actuator and the tissue penetrating member are separate parts.

Seek A16

130. A method for treating cardiac tissue comprising the steps of:

providing an intravascular catheter of the type having an elongate catheter body and a tissue penetrating member disposed proximate a distal portion of the catheter body, the penetrating member having a first non-penetrating position and a second tissue penetrating position;

navigating the catheter through vasculature to a treatment site;

moving the tissue penetrating member from one of the first or second positions to the other of the first or second positions; and

delivering a drug to the treatment site wherein the drug is selected from the group consisting of: a peptide, a protein and a fragment thereof.

131. A method for treating cardiac tissue as in claim 130, wherein the drug is recombinant.

Seek A17

132. A method for treating cardiac tissue comprising the steps of:

providing an intravascular catheter of the type having an elongate catheter body and a tissue penetrating member disposed proximate a distal portion of the catheter body, the penetrating member having a first non-penetrating position and a second tissue penetrating position;

navigating the catheter through vasculature to a treatment site;

moving the tissue penetrating member from one of the first or second positions to the other of the first or second positions; and

delivering a drug comprising a genetic material to the treatment site.

133. A method for treating cardiac tissue as in claim 131 wherein the genetic material, when incorporated into the tissue, results in the expression of therapeutic materials.

129 127
~~134.~~ A method of treating cardiac tissue as in claim ~~132~~ wherein the cardiac tissue comprises ischemic tissue.

130 127
~~135.~~ A method of treating cardiac tissue as in claim ~~132~~ wherein the cardiac tissue comprises an artery.

131 130
~~136.~~ A method of treating cardiac tissue as in claim ~~135~~ wherein the artery is subject to stenosis or restenosis.

132 130
~~137.~~ A method of treating cardiac tissue as in claim ~~135~~ wherein the cardiac tissue is subject to atherosclerosis.

133 ~~138~~. A method of treating cardiac tissue as in claim 127 ~~132~~ wherein the cardiac tissue is diseased.

Sub a18 139. A method of treating cardiac tissue as in claim 132 wherein the drug is delivered outside the wall of a coronary vessel.

140. A method for treating cardiac tissue comprising the steps of:

providing an intravascular catheter of the type having an elongate catheter body and a tissue penetrating member disposed proximate a distal portion of the catheter body, the penetrating member having a first non-penetrating position and a second tissue penetrating position;

navigating the catheter through vasculature to a treatment site;

moving the tissue penetrating member from one of the first or second positions to the other of the first or second positions; and

delivering a drug to the treatment site wherein the drug is selected from the group consisting of: heat shock protein, a hormone, ATP, an ATP precursor, glucose, and a metabolic intermediate.

141. A method for treating cardiac tissue as in claim 140, wherein the drug provides a cardioprotective effect.

Sub a19 142. A method for treating cardiac tissue comprising the steps of:

providing an intravascular catheter of the type having an elongate catheter body and a tissue penetrating member disposed proximate a distal portion of the catheter

body, the penetrating member having a first non-penetrating position and a second tissue penetrating position;

navigating the catheter through vasculature to a treatment site;

moving the tissue penetrating member from one of the first or second positions to the other of the first or second positions; and

delivering a drug comprising glycoprotein or a fragment thereof to the treatment site.

143. A method for treating cardiac tissue comprising the steps of:

providing an intravascular catheter of the type having an elongate catheter body, a tissue penetrating member disposed proximate a distal portion of the catheter body, the penetrating member having a first non-penetrating position and a second tissue penetrating position, and further having an actuator member disposed proximate a distal portion of the catheter body for moving the tissue penetrating member from one of the first or second positions to the other of the first or second positions;

navigating the catheter through vasculature to a treatment site;

actuating the tissue penetrating member whereby the tissue penetrating member moves from one of the first or second positions to the other of the first or second positions; and

delivering a drug to the treatment site wherein the drug is selected from the group consisting of: a peptide, a protein and a fragment thereof.

139 138

~~144~~. A method of treating cardiac tissue as in claim ~~143~~ wherein the actuator and the tissue penetrating member are integrally formed.

140 138

~~145~~. A method of treating cardiac tissue as in claim ~~143~~ wherein the actuator and the tissue penetrating member are separate parts.

146. A method for treating cardiac tissue as in claim 143, wherein the peptide, protein or fragment thereof is recombinant.

147. A method for treating cardiac tissue comprising the steps of:

providing an intravascular catheter of the type having an elongate catheter body, a tissue penetrating member disposed proximate a distal portion of the catheter body, the penetrating member having a first non-penetrating position and a second tissue penetrating position, and further having an actuator member disposed proximate a distal portion of the catheter body for moving the tissue penetrating member from one of the first or second positions to the other of the first or second positions;

navigating the catheter through vasculature to a treatment site;

actuating the tissue penetrating member whereby the tissue penetrating member moves from one of the first or second positions to the other of the first or second positions; and

delivering a drug comprising a genetic material to the treatment site.

143
~~148~~. A method of treating cardiac tissue as in claim 147 wherein the actuator and the tissue penetrating member are integrally formed.

144
~~149~~. A method of treating cardiac tissue as in claim 147 wherein the actuator and the tissue penetrating member are separate parts.

145
~~150~~. A method for treating cardiac tissue as in claim 147 wherein the genetic material, when incorporated into the tissue, results in the expression of therapeutic materials.

151. A method for treating cardiac tissue comprising the steps of:

providing an intravascular catheter of the type having an elongate catheter body, a tissue penetrating member disposed proximate a distal portion of the catheter body, the penetrating member having a first non-penetrating position and a second tissue penetrating position, and further having an actuator member disposed proximate a distal portion of the catheter body for moving the tissue penetrating member from one of the first or second positions to the other of the first or second positions;

navigating the catheter through vasculature to a treatment site;

actuating the tissue penetrating member whereby the tissue penetrating member moves from one of the first or second positions to the other of the first or second positions; and

delivering a drug to the treatment site wherein the drug is selected from the group consisting of: heat shock protein, a hormone, ATP, an ATP precursor, glucose, and a metabolic intermediate.

152. A method of treating cardiac tissue as in claim 151 wherein the actuator and the tissue penetrating member are integrally formed.

153. A method of treating cardiac tissue as in claim 151 wherein the actuator and the tissue penetrating member are separate parts.

154. A method for treating cardiac tissue as in claim 151, wherein the drug provides a cardioprotective effect.

155. A method for treating cardiac tissue comprising the steps of:

providing an intravascular catheter of the type having an elongate catheter body, a tissue penetrating member disposed proximate a distal portion of the catheter body, the penetrating member having a first non-penetrating position and a second tissue penetrating position, and further having an actuator member disposed proximate a distal portion of the catheter body for moving the tissue penetrating member from one of the first or second positions to the other of the first or second positions;

navigating the catheter through vasculature to a treatment site;

actuating the tissue penetrating member whereby the tissue penetrating member moves from one of the first

or second positions to the other of the first or second positions; and

delivering a drug comprising a glycoprotein or a fragment thereof to the treatment site.

156. A method of treating cardiac tissue as in claim 155 wherein the actuator and the tissue penetrating member are integrally formed.

157. A method of treating cardiac tissue as in claim 155 wherein the actuator and the tissue penetrating member are separate parts.

158. A method for treating cardiac tissue as in claim 155, wherein the drug is recombinant.

159. A method for treating cardiac tissue as in claim 142, wherein the drug is recombinant.

160. A method of treating cardiac tissue as in claim 132 wherein the cardiac tissue comprises pericardium.

161. A method of treating cardiac tissue as in claim 132 wherein the cardiac tissue comprises endocardium.

162. A method of treating cardiac tissue as in claim 132 wherein the cardiac tissue comprises myocardium.

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